

Reply to Office communication of Sept. 29, 2006
Correction to Non-Compliant Amdt. dated Sept. 18, 2006

Appl. No. 09/816,472
Reply dated Oct. 29, 2006

AMENDMENTS TO THE CLAIMS

Please amend the claims as follows:

1. (Currently amended): A microprobe device for providing a signal to an external analyte meter indicating analyte presence in an analyte-containing bodily fluid of a subject, comprising:

a single-crystal silicon substrate having an X length dimension and a Y width dimension and a Z thickness dimension, and having a front side and a back side extending in the X and Y dimensions;

a body portion formed entirely by the single-crystal silicon substrate;

a microprobe portion formed entirely by the single-crystal silicon substrate, the microprobe portion having a body end connected to the body portion, and having a penetration end extending away from the body portion in the X length dimension for penetrating into the subject to access the fluid;

a biosensor integrated into the single-crystal silicon substrate, for sensing analyte presence and for providing a signal in response to the analyte presence, and;

the microprobe device being absent a closed fluid channel in any portion of the device that passes/penetrates into the subject during penetration to access the fluid.

2. (Previously presented): The device of claim 1, wherein the microprobe portion is smoothly width tapered along substantially the entire X length dimension, converging from a larger Y width dimension at the body end to a smaller Y width dimension at the penetration end.

3. (Previously presented): The device of claim 2, wherein the convergence of the microprobe taper is uniform establishing a constant change in the Y width dimension.

4. (Previously presented): The device of claim 2, wherein the convergence of the microprobe taper establishes a continuous change in the Y width dimension for optimizing stress distribution during penetration.

5. (Previously presented): The device of claim 1, wherein the Y width of the microprobe portion is about 200 micrometers at the body end and about 30 micrometers at the penetration end.

6. (Previously presented): The device of claim 1, wherein the X length of the microprobe portion is from about 0.5 mm to about 2.5 mm.

7. (Previously presented): The device of claim 1, wherein the microprobe portion has a penetration depth of from about 0.5 mm to about 2 mm.

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Correction to Non-Compliant Amdt. dated Sept. 18, 2006**

**Appl. No. 09/816,472
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8. (Previously presented): The device of claim 1, wherein the X length of the body portion is from about 0.3 mm to about 2 mm, and the Y width of the body portion is from about 0.3 mm to about 2 mm.
9. (Previously presented): The device of claim 1, wherein the Y width dimension of the microprobe portion terminates in a chisel shaped point at the penetration end.
10. (Previously presented): The device of claim 1, wherein the Y width dimension of the microprobe portion terminates in a symmetrically shaped point at the penetration end.
11. (Previously presented): A microprobe device for providing a signal to an external analyte meter indicating analyte presence in an analyte-containing bodily fluid of a subject, comprising:
a silicon substrate having an X length dimension and a Y width dimension and a Z thickness dimension, and having an front side and a back side extending in the X and Y dimensions;
a body portion formed by the silicon substrate; a microprobe portion formed by the silicon substrate, having a body end connected to the body portion, and having a penetration end extending away from the body portion in the X length dimension for penetrating into the subject to access the fluids; and biosensor integrated into the silicon substrate, for sensing analyte presence and for providing a signal in response to the analyte presence; and
a silicon microfillet portion at the connection between the body end of the microprobe portion and the body portion.
12. (Previously presented): The device of claim 1, further comprising a signal interface structure integrated into the silicon substrate on the body portion thereof for interfacing with an analyte meter; and a signal carrier integrated into the silicon substrate between the biosensor and interface structure for carrying the signal.
13. (Previously presented): The device of claim 12, wherein the biosensor is an electrobiosensor, the signal is carried by electrical energy, the signal carrier is a pair of electrically conductive leads, and the interface structure is a pair of electrically conductive contacts.
14. (Previously presented): The device of claim 13, wherein the biosensor is an electrochemical biosensor responsive to the analyte presence by altering the electrical energy of the signal.
15. (Previously presented): The device of claim 14, wherein the alteration in the electrical energy of the signal is proportional to the concentration of the analyte presence.

**Reply to Office communication of Sept. 29, 2006
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16. (Previously presented): The device of claim 13, wherein the biosensor is an oscillating electrogravimetric biosensor responsive to the analyte presence by altering oscillation frequency.
17. (Previously presented): The device of claim 16, wherein the alteration in the oscillation frequency indicates the concentration of the analyte presence.
18. (Previously presented): The device of claim 13, further comprising an electrically insulative layer on the silicon substrate.
19. (Previously presented): The device of claim 18, wherein the insulative layer is a silicon oxide film.
20. (Previously presented): The device of claim 18, wherein the biosensor is deposited on the insulative layer.
21. (Previously presented) The device of claim 18, wherein the conductive leads and the conductive contacts are conductive metal deposited on the insulative layer.
22. (Previously presented): The device of claim 18, wherein the conductive leads and conductive contacts are conductive carbon deposited on the insulative layer.
23. (Previously presented): The device of claim 18, wherein the conductive leads and conductive contacts are doped silicon.
24. (Previously presented): The device of claim 18, wherein the silicon substrate is sufficiently doped to form one of the pair of conductive leads and one of the pair of conductive contacts.
25. (Previously presented): The device of claim 12, wherein the biosensor is an optical biosensor, the signal is alterations in photon energy, the signal carrier is an optrode; and the interface structure is an optical coupler.
26. (Previously presented): The device of claim 1, wherein the biosensor is positioned on the microprobe portion sufficiently distant from the body end to pass into the subject during penetration.
27. (Previously presented): The device of claim 1, wherein the biosensor is positioned on the microprobe portion near the penetration end.

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Correction to Non-Compliant Amdt. dated Sept. 18, 2006

Appl. No. 09/816,472
Reply dated Oct. 29, 2006

28. (Withdrawn): The device of claim 1, wherein the biosensor is on the microprobe portion near the body end or on the body portion.

29. (Withdrawn – currently amended): The device of claim 28, further comprising an open fluid channel formed in the substrate ~~microprobe portion~~ between the penetration end and the biosensor for transporting analyte fluid to the biosensor by capillary action.

30. (Withdrawn): The device of claim 29, wherein open fluid channel is a V-groove etched in the silicon of the microprobe portion.

31. (Previously presented): The device of claim 1, wherein the surface of the side of the silicon substrate is planar, and the biosensor is deposited onto the planar surface.

Claims 32-33. (Canceled)

34. (Previously presented): The device of claim 1, further comprising multiple biosensors integrated into either or both sides of the silicon substrate.

35. (Canceled)

36. (Previously presented): The device of claim 34, wherein each of the multiple biosensors is positioned at a different location along the X dimension of the microprobe to sense analyte presence at a different penetration depth.

37. (Previously presented): The device of claim 1, wherein the silicon substrate is formed of single crystal silicon.

38. (Withdrawn): An analyte monitoring assembly for emplacement on a subject which provides a transmitted signal to an external analyte meter indicating analyte presence in an analyte-containing fluid of the subject, comprising: a base member having an in vivo face disposed toward the subject when emplaced; a silicon substrate member mounted on the base member having an X length dimension generally normal to the in vivo face of the base member; a body portion formed by the silicon substrate member; a signal transmitter on the body portion for providing the transmitted signal; is a microprobe portion formed by the silicon substrate member on the in vivo face of the base member, having a body end connected to the body portion, and having a penetration end extending away from the body portion in the X length dimension for penetrating into the subject to access the analyte-containing fluid; biosensor on the silicon substrate member for sensing analyte presence and for providing a sensed signal in response to

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Correction to Non-Compliant Amdt. dated Sept. 18, 2006

Appl. No. 09/816,472
Reply dated Oct. 29, 2006

the analyte presence; and signal carrier deposited on the silicon substrate member between biosensor and transmitter for carrying the sensed signal to the transmitter.

39. (Withdrawn): The device of claim 38, wherein the in vivo face of the base member has a stabilizing surface for engaging the subject to maintain the penetration orientation of the microprobe portion.

40. (Withdrawn): The device of claim 39, further comprising an adhesive on the stabilizing surface for retaining the assembly in place during emplacement.

41. (Withdrawn): The device of claim 39, wherein the stabilizing surface limits the penetration of the microprobe portion into the subject.

42. (Withdrawn): The device of claim 38, further comprising an analog to digital converter for converting the sensed signal from the biosensor into a digital transmitted signal.

43. (Withdrawn): The device of claim 38, further comprising a power source on the body portion for activating the signal transmitter.

44. (Withdrawn): The device of claim 38, wherein the signal transmitter and the power source are deposited into the silicon forming the body portion of the silicon substrate.

45. (Withdrawn) The device of claim 38, further comprising a cover member over the body portion of the substrate and engaging the base member for sealing the assembly.

46. (Withdrawn): The device of claim 38, wherein the monitoring assembly is emplaced for a single transmission.

47. (Withdrawn): The device of claim 38, wherein the monitoring assembly is emplaced for continuous transmission.

48. (Previously presented): A microprobe device for providing a signal to an external analyte meter indicating analyte presence in an analyte-containing bodily fluid of a subject, comprising:

a silicon substrate having an X length dimension and a Y width dimension and a Z thickness dimension, and having a front side and a back extending in the X and Y dimensions and a cavity extending into the silicon substrate in the Z thickness dimension;

a body portion formed by the silicon substrate;

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Appl. No. 09/816,472
Reply dated Oct. 29, 2006

a microprobe portion formed by the silicon substrate, having a body end connected to the body portion, and having a penetration end extending away from the body portion in the X length dimension for penetrating into the subject to access the fluids; and
a biosensor integrated into the silicon substrate, for sensing analyte presence and for providing a signal in response to the analyte presence, the biosensor being deposited onto the silicon within the cavity.

49. (Previously presented): The microprobe device of claim 48 wherein the cavity extends completely through the substrate in the Z thickness dimension.

50. (Previously presented): A microprobe device for providing a signal to an external analyte meter indicating analyte presence in an analyte-containing bodily fluid of a subject, comprising:

a silicon substrate having an X length dimension and a Y width dimension and a Z thickness dimension, and having a front side and a back side extending in the X and Y dimensions;

a body portion formed by the silicon substrate;

a microprobe portion formed by the silicon substrate, having a body end connected to the body portion, and having a penetration end extending away from the body portion in the X length dimension for penetrating into the subject to access the fluids; and

at least one biosensor integrated into each side of the silicon substrate, for sensing analyte presence and for providing a signal in response to the analyte presence, wherein each of the biosensors senses the presence of a different analyte.

Claims 51-56. (Canceled)

57. (Currently amended): The microprobe device of claim 1 wherein ~~the entire area~~ any part of the microprobe portion that passes into the subject during penetration to access the bodily fluids tip and of an adjacent portion of the penetration end extending at least 50% of the distance from the tip towards the body end of the microprobe, has a uniform thickness in the Z direction that is less than the thickness of the body portion, ~~the body portion having a thickness of 500 micrometers;~~ and

~~a biosensor integrated into the silicon substrate, for sensing analyte presence and for providing a signal in response to the analyte presence.~~

58. (Previously presented): The microprobe device of claim 48 wherein the silicon wafer is a single crystal.

Reply to Office communication of Sept. 29, 2006
Correction to Non-Compliant Amdt. dated Sept. 18, 2006

Appl. No. 09/816,472
Reply dated Oct. 29, 2006

59. (Canceled)

60. (Previously presented): The microprobe of claim 5, wherein the Y width of the microprobe portion has a width of about 200 micrometers at the body end and a width of about 30 micrometers at a point between a beginning of the penetration end and a termination of the penetration end.

Claims 61-63. (Canceled)

64. (Currently amended): The microprobe device of claim 57, wherein ~~the entire area~~any part of the microprobe portion that passes into the subject during penetration to access the bodily fluids tip and of an adjacent portion of the penetration end extending at least 50% of the distance from the tip towards the body end of the microprobe, has a uniform thickness in the Z direction of at least 50 micrometers.

65. (Currently amended): The microprobe device of claim 64, wherein ~~the entire area~~any part of the microprobe portion that passes into the subject during penetration to access the bodily fluids tip and of an adjacent portion of the penetration end extending at least 50% of the distance from the tip towards the body end of the microprobe, has a substantially uniform thickness in the Z direction of at least about 100 micrometers ~~that is less than the thickness of the body portion, the body portion retaining the initial thickness of the silicon substrate.~~

66. (Canceled)

67. (Currently amended): A microprobe device providing a signal to an external analyte meter indicating analyte presence in an analyte-containing bodily fluid of a subject, comprising:

- a silicon substrate having an X length dimension and a Y width dimension and a Z thickness dimension, and having a front side and a back side extending in the X and Y dimensions;

- a body portion formed entirely by the silicon substrate;

- a microprobe portion formed entirely by the silicon substrate, the microprobe portion having a body end connected to the body portion, and having a penetration end extending away from the body portion in the X length dimension for penetrating into the subject to access the fluid; and;

**Reply to Office communication of Sept. 29, 2006
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a biosensor integrated into the silicon substrate, for sensing analyte presence and for providing a signal in response to the analyte presence, and;

the microprobe device being absent a closed fluid channel in any portion of the device that ~~passes~~ penetrates into the subject during penetration to access the fluid.

Claims 68-71. (Canceled)